

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: GADOLINIUM-BASED)	Case No. 1:08 GD 50000
CONTRAST AGENTS PRODUCTS)	MDL No. 1909
LIABILITY LITIGATION)	Judge Dan Aaron Polster
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)	Case No. 1:12 GD 50004
Paul Decker et al.,)	<u>MEMORANDUM OF OPINION</u>
- against -)	<u>AND ORDER</u>
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GE Healthcare, Inc., et al.,)	
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Before the Court are the following pending motions in limine filed by Plaintiffs:

1. **To prohibit GEHC and its witnesses from speculating that the FDA wanted to “take the lead” on labeling.**

Plaintiffs seek to prohibit GEHC and its witnesses from arguing or suggesting that it did not make a labeling change to contraindicate or warn about NSF because the FDA “wished to take the lead” on this issue. The particular testimony Plaintiffs are concerned about is that of Dr. David Feigal, a former FDA employee who now consults on FDA regulatory matters and is an expert in drug labeling, FDA regulation, and clinical epidemiology. In his expert report, Dr. Feigal writes that the FDA made it clear to GEHC that the “FDA wished to take lead on” the Omniscan labeling and that “GE Healthcare acted prudently and responsibly in working cooperatively with FDA, rather than acting unilaterally to institute a labeling change that,

ultimately, was not the direction chosen by FDA.” (Doc. #:103-1 at 26). Moreover, GEHC, in its opposition brief, avers that the FDA wished to impose class labeling for all GBCAs rather than piecemeal warnings for particular products. (Doc. # 135 at 2).

Consistent with this Court’s ruling in a prior case in this MDL, Dr. Feigal may not speculate about the FDA’s knowledge or state of mind, such as whether it wished to take the lead on labeling, and GEHC may not offer hearsay evidence to prove the same. (*Knase et al. v. General Elec. Co. et al.*, 1:08 GD 50026, Doc. # 261 at 10). Furthermore, as to the question of whether GEHC acted reasonably and prudently, the Court will not “permit Defendants to argue or imply that GEHC could not have unilaterally changed Omniscan’s label without FDA approval.” (Id. at 10-11). Indeed, drug manufacturers, not the FDA, “bear primary responsibility for their drug labeling at all times.” *Wyeth v. Levine*, 555 U.S. 555, 579 (2009). GEHC cannot hide behind the FDA’s decision to approve the Omniscan labeling; the FDA’s actions do not relieve GEHC of its primary, independent, duty to warn.

Accordingly, the motion is **GRANTED**.

2. To exclude or limit GEHC and its witnesses from presenting evidence of Mr. Decker’s history of smoking.

Plaintiffs contend that there are only three legitimate bases for GEHC to attempt to introduce limited evidence of Mr. Decker’s smoking history. First, it might be relevant to show that Mr. Decker is a “risk taker”—if that were an issue in this case. Second, it could be relevant if smoking were a risk factor for NSF. Third, it might be relevant to show a diminished life expectancy.

Plaintiffs argue that smoking is not relevant in this case since Mr. Decker’s risk taking is

not an issue and that smoking is not a risk factor for NSF. Plaintiffs also argue that while smoking may be marginally relevant to life expectancy, that is not the case here since GEHC's experts do not rely on life expectancy data for smokers. Plaintiffs argue that GEHC's expert, Dr. Weisbord, relies solely and exclusively on the life expectancy table for patients with end-stage renal disease and does not refer to "life tables" for smoking to support his opinions.

The Court finds that Mr. Decker's history of smoking is relevant to his diminished life expectancy. Of course, GEHC cannot, without proper evidence—such as an expert witness armed with the appropriate life-expectancy data—quantify the degree to which smoking reduces Mr. Decker's life expectancy. But it is common knowledge that smoking is adverse to one's health, and so a jury may conclude—and GEHC may argue—that, by smoking, Mr. Decker has voluntarily diminished his overall health and his life expectancy, and the jury may consider this in awarding damages. But GEHC may not, without supporting evidence, argue that Mr. Decker's smoking has prevented him from receiving a kidney transplant.

Motion **DENIED**.

3. To exclude or limit GEHC and its witnesses from arguing or suggesting that Mr. Decker's esophageal cancer is related to smoking.

Plaintiffs wish to exclude or limit GEHC and its witnesses from arguing or suggesting that Mr. Decker's esophageal cancer is related to his smoking. Plaintiffs contend that Mr. Decker's esophageal cancer is not caused by smoking, but by an irritation of his esophagus called "Barrett's Esophagus."

GEHC may argue that Mr. Decker's smoking is related to his esophageal cancer (which the jury may consider on the issues of damages) provided it has the proper evidence. And GEHC appears to have such evidence, namely the testimony of Plaintiffs' own expert, Dr. Derek

Fine, who opines that esophageal cancer is associated with smoking, and the testimony of GEHC's own expert, Dr. Steven Weisbord, who likewise thinks smoking is "strongly associated with the development of esophageal cancer." (Doc. # 135-8 at 6-7).

Critically, Plaintiffs are not challenging these experts, or their statements about smoking and esophageal cancer, on *Daubert* grounds. Rather, they challenge the conclusion that an association between smoking and esophageal cancer establishes a causal nexus. But the best remedy for questionable expert conclusions is to subject them to the crucible of an adversarial trial—through cross-examination and competing expert testimony—and ultimately let the jury evaluate the opinions. The proper remedy is not to exclude the evidence ahead of trial.

Accordingly, the motion is **DENIED**.

4. To exclude testimony, or argument, that Mr. Decker's NSF occurred as a result of "co-factors"

Plaintiffs wish to exclude testimony and argument that Mr. Decker's NSF occurred as a result of co-factors, including infection or a pro-inflammatory state. GEHC thinks this evidence touches on two key issues of consequence: breach and causation.

As to the issue of breach, GEHC writes, "[e]vidence of co-factors will be important to the jury question of whether GEHC should have known that a small number of patients who were both administered Omniscan and had certain other co-factors might develop NSF." (Doc #: 135, at 12.). This evidence is indeed helpful on the issue of breach because, if it is true that NSF appears only in a tiny subset of the population—and, even then, only among those with a unique constellation of factors—then it may have been difficult in 2005 for GEHC to foresee the magnitude of the risk of administering Omniscan.

As to the issue of causation, GEHC contends that NSF develops only in combination with

other factors, and that those other factors are important for the jury to know so they can properly analyze the issue of causation. Plaintiffs contend that the only thing they must establish under Ohio law is that “Omniscan was ‘a’ cause, not the ‘sole cause’ of Plaintiff’s NSF.” (Doc. # 103 at 18). The answer lies somewhere in between.

Plaintiffs *do* have to establish that Omniscan was “a” (*i.e.*, a but-for) cause of NSF. But they *also* must prove legal (*i.e.*, proximate) cause. The Ohio Jury Instructions state the applicable rule: “There may be more than one (proximate) (direct) cause. The fact that some other cause combined with the negligence of a defendant in producing an injury does not relieve him/her from liability, unless it is shown such other cause would have produced the injury *independently* of that defendant’s negligence.” 1-CV 405 OJI CV 405.01(3)(B) (Last Revised 12-11-10) (emphasis added). In this case, if Omniscan was a proximate cause, then, assuming the other elements are established, GEHC may be liable, even though there may have been other factors that combined with Omniscan to produce NSF—unless, of course, GEHC can prove that Mr. Decker’s NSF would have occurred independently of his exposure to Omniscan.

As to the definition of proximate cause, the Ohio Jury Instructions, once again, provide guidance: “(Proximate)(direct) cause is an act or failure to act that in the natural and continuous sequence directly produced the (injury) (death) (physical harm) and without which it would not have occurred.” *Id.* at 405.01(2).

And as to whether or not Plaintiffs must show that Omniscan was a “substantial factor” in bringing about NSF, the answer is yes. *See RESTATEMENT (SECOND) OF TORTS § 431 (1965)* (an “actor’s negligent conduct is a legal cause of harm to another if [] his conduct is a substantial factor in bringing about the harm”); *Horton v. Harwick Chem. Corp.*, 73 Ohio St. 3d 679, 686

(1995) (citing with approval § 431 of the Restatement).

While we are on the subject, the Court will disabuse GEHC of its mistaken notion, expressed in its Trial Brief, that Plaintiffs must show by a preponderance of the evidence “that NSF was a foreseeable consequence of administering Omniscan to Mr. Decker.” (Doc. # 149 at 12-13). GEHC reiterates the point a page later: “Plaintiffs must prove that *NSF* was a reasonably foreseeable risk associated with Omniscan....” (Id. at 14) (original emphasis). But the burden is not so stringent. The Ohio Jury Instructions state: “The test for foreseeability is not whether a person should have foreseen the (injuries) (damages) *exactly as it happened to the specific [person]*.” 1-CV 401 OJI CV 401.07(2) (Last Revised 5-12-12). Rather, the test is whether a reasonably careful person in the defendant’s position would have anticipated that an act or failure to act would likely result in the *type* of injuries the plaintiff suffered. *Id.*; see also 1-CV 451 OJI CV 451.07(1)(A)(2) (instructing that an element of a failure-to-warn claim is that the manufacturer failed to warn “in light of the likelihood that the product would cause harm *of the type* claimed by the plaintiff...”) (emphasis added).

For the reasons explained, the motion is **DENIED**.

5. To exclude evidence of testimony regarding why Mr. Decker left the care of Stephen Lutz, M.D.

Plaintiffs wish to exclude any evidence or testimony regarding the reasons why Mr. Decker left the care of his first oncologist, Stephen Lutz, M.D., and the subsequent medical records memorializing Dr. Lutz’s refusal to treat Mr. Decker and his conversations with the Deckers regarding the same. GEHC has said it will not use this evidence at trial. (Doc. # 135 at 18) (“GEHC has no intention of using this document at trial....”). The motion is therefore **DENIED** as moot.

IT IS SO ORDERED.

/s/ Dan A. Polster February 15, 2013

Dan Aaron Polster
United States District Judge